UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,492	01/10/2001	Svetlana Dolina	1067/2	1483

7590 12/21/2007

Mark Friedman
c/o Bill Polkinghorn Discovery Dispatch
9003 Florin Way
Upper Marlboro, MD 20772

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
12/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,492	DOLINA ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-73 and 75-93* is/are pending in the application.

4a) Of the above claim(s) *72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-71,73 and 75-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Response to Amendment

2. Claims 68-73 and 75-93 have been amended and claim 74 has been cancelled as requested in the amendment filed on July 12, 2007. Following the amendment, claims 67-73 and 75-93 are pending in the instant application.

Claim 72 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Election was made without traverse in Paper No. 8.

Claims 67-71, 73 and 75-93, in so far as they are directed to the elected species, KA and KA metabolites, are under examination in the instant office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Objections

4. Claim 67, as amended, is objected to because of the following informalities: claim 67 has a period in the middle of the claim.

MPEP 608.01(m), Form of Claims, states:

Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 67-71, 73 and 75-93, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 67 and 93, as currently presented, are vague and ambiguous for recitation of "medical condition is related to epilepsy". One skilled in the art readily appreciates that there are many conditions "related to epilepsy", such as conditions having the same symptoms as epilepsy (meningitis, encephalitis, migraine headaches, eclampsia) or symptoms that looks like seizures (narcolepsy, Tourette's syndrome), etc. Since the instant specification fails to present a clear definition of "related to epilepsy conditions" and this term is not defined by art accepted terminology, the metes and bounds of the recitation cannot be determined. This is especially true with respect to the claims 78-79, which recite "an individual without said medical condition" and "an individual with said medical condition". Unless the condition is clearly defined, the skilled practitioner would not be able to appraise the scope of the claimed subject matter.

8. Further, claims 67, 81-82, 86 and 88 are directed to methods comprising the steps of "diagnosing" and "comparing", "defining", "noting" and "adjusting". These steps can all be performed by mental thought processes, which raises issues of non-statutory subject matter.

To satisfy the requirement of 35 U.S.C. 101, a method or process claim must include a step of a physical transformation, or produce a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.,* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999)). In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

In the instant case, the specificity of the methods hinges upon measuring KA metabolites in samples for diagnostic purposes. Since the steps of the claims can be performed by mental thought processes, they are subjective and thus lack the concrete standard of reproducible results. To satisfy the requirements of 35 U.S.C. 101 and 112, second paragraph, the claims should include definitive steps to clearly indicate as what step leads to diagnosis of the clinical condition. For example, if it is the increase of the concentration of kynurenine metabolites that indicates that a subject has a medical condition related to epilepsy, then that what the claim must recite.

9. Claims 68, 70 and 90 are vague and ambiguous for recitation of "neuroprotective metabolites" and "neurotoxic metabolites". The metes and bounds of the recitations cannot be

determined from the claims or the instant specification as filed. Applicant is advised that because the instant specification fails to define these terms, to disclose a representative number of species within each genus, or to describe in written terms as how these metabolites look like, the presence of these limitations raises potential issues of lack of written description under 112, first paragraph.

10. Claims 84-86 do not make sense. Claim 84 lacks antecedent basis for recitation of "anti-epileptic drug" in claim 67, and the relevance of measuring amount and concentration of the drug is not obvious. Applicant is advised to rewrite the claims to better express the claimed subject matter.

11. Claim 88 recites the limitation "treatment regiment" in claim 87. There is insufficient antecedent basis for this limitation in the claim because claim 87 depends from claim 67, which is limited to a diagnostic method only. Clarification is required.

12. Claim 89 is indefinite as being incomplete for omitting essential cooperative relationships of elements, such omission amounting to a gap between the necessary connections. See MPEP § 2172.01. Specifically, the claim recites "a system for diagnosis comprising" (1) a sample and (2) a device to measure concentrations and to compare concentrations, which leaves the element of diagnosis missing.

13. Claims 69, 71, 73, 75-77, 80, 83, 87 and 91-92 are indefinite for being dependent from indefinite claims.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 67-71 and 75-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Munoz-Hoyos et al. , Clin. Endocrinology, 1997, 47, pp. 667-77.

Claims 67-71, 73 and 75-80 are broadly directed to methods of diagnosis of epilepsy by measuring and comparing the concentration of at least two kynurenine metabolites in samples obtained from subjects. Publication of Munoz-Hoyos et al. discloses measurement of kynurenine metabolites (specifically kynurenine, kynurenine acid and 3HOAA) in samples obtained from patients suffering from different epileptic conditions and normal individuals (control), see Tables 1, 2 and 3 and the whole paper. Note that since claim 67 fails to clearly define what represents condition related to epilepsy or what stands for diagnosis of that condition, the measurements of kynurenine metabolites in samples obtained from individuals suffering from various epileptic condition (representing "condition related to epilepsy") and from various control groups (representing "individuals without said medical condition" and those "substantially free of clinical manifestations indicative of epilepsy" as well as "predisposition to epilepsy") fully anticipate the instant claimed methods, as currently claimed.

16. Claims 67-71, 73, 75-80 and 84-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Heyes et al., 1994, Epilepsia, 35(2), pp. 251-7. Claims 67-71, 73, 75-80 are broadly directed to methods of diagnosis of epilepsy by measuring and comparing the concentration of at least two kynurenine metabolites in samples obtained from subjects. Claims

84-88, by broadest reasonable interpretation, encompass measuring and comparing the concentration of at least two kynurenine metabolites in samples obtained from subjects treated with anti-epileptic drugs. Document of Heyes et al. teaches measurement of kynurenine metabolites (specifically kynurenine, kynurenine acid, 3HOAA and QUIN) in samples obtained from patients suffering from different epileptic conditions, normal individuals and patients undergoing treatment with antiepileptic drugs (see abstract, pp. 252-254 and Figure 2), thus, fully anticipating the instant claimed methods, as currently written.

Conclusion

17. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

December 18, 2007